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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,418	05/09/2002	Matthew Morell	127-01	1169

23713 7590 01/31/2005

GREENLEE WINNER AND SULLIVAN P C  
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SUITE 200  
BOULDER, CO 80301

EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/018,418

Applicant(s)

MORELL ET AL.

Examiner

Ashwin Mehta

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004 and 04 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 67-75,80,82 and 85-91 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-70,72,74,75,80,82 and 85-91 is/are rejected.
- 7) ☒ Claim(s) 71 and 73 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 09 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10062004.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objections to the specification are withdrawn in light of the amendments.
3. The objections to claims 68, 72, 75, 82, 87, and 88 are withdrawn in light of the claim amendments.
4. The rejection of claims 68-70, 72, and 80-85 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph is withdrawn in light of the claim amendments or cancellations.
5. The rejections of claims 67, 68, 70, 72, 74, 75, 80-83, and 85-91 under 35 U.S.C. 102(b) and 102(e) are withdrawn, in light of the claim amendments.

### ***Claim Objections***

6. Claim 73 remains and claim 71 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 74 remains objected to for reciting, "isolate" instead of --isolated-- in line 2.

***Claim Rejections - 35 USC § 112***

7. Claims 68, 69, 72, 75, 80, 82, and 85 remain and claims 67, 70 74, and 86-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed April 2, 2004. Applicants traverse the rejection in the paper filed October 4, 2004. Applicants' arguments were fully considered but were not found fully persuasive.

Applicants argue that the claim amendments render the rejection moot (response, page 23, 4<sup>th</sup> full paragraph). However, the claims still encompass nucleic acid molecules that can encode any starch synthase activity. The specification indicates that four classes of starch synthases have been identified in plants: GBSS, SSI, SSII, and SSIII (page 8, lines 8-15). SEQ ID NO: 4 is an SSII enzyme. The nucleotide sequence of SEQ ID NO: 3 and the amino acid sequence of SEQ ID NO: 4 are not correlated with any other type of activity. It is suggested that the claims be amended to indicate that the starch synthase is starch synthase --II--. It is also noted that claim 75 encompasses SEQ ID NOs: 26 and 27. It is suggested that parts (i) and (ii) of claim 75 be removed. As discussed in the last Office action, those sequences are found within non-elected SEQ ID NO: 1.

8. Claims 68, 69, 72, 75, 80, 82, and 85 remain and claims 67, 70 74, and 86-91 are rejected under 35 U.S.C. 112, first paragraph, for lacking enablement for the full scope of the claims, for

the reasons of record stated in the Office action mailed April 2, 2004. Applicants traverse the rejection in the paper filed October 4, 2004. Applicants' arguments were fully considered but were not found fully persuasive.

Applicants argue that the claim amendments render the rejection moot (response, page 26, 5<sup>th</sup> full paragraph). However, the claims still encompass isolated nucleic acid molecules that can encode any starch synthase enzyme, whereas SEQ ID NO: 4 is a starch synthase II. It is also noted that claim 75 still encompasses probes and primers set forth in SEQ ID NOs: 26 and 27. However, as noted in the last Office action, SEQ ID NOs: 25-28 are in non-elected SEQ ID NO: 1. It is again suggested that the claims be amended as discussed above.

Further, claim 80 still indicates that the enzyme activity of one or more starch synthase isoenzymes is modified. As discussed previously, the specification does not indicate how enzyme activity, as opposed to nucleic acid expression, is affected by the claimed method. It is suggested that lines 5-6 of the claim be amended to indicate that the expression level of starch synthase II is decreased.

Further, regarding claim 91, it is unclear how one skilled in the art is to use a gene construct or vector comprising the probe or primer of claim 74. Probes and primers are used in hybridization or PCR methods. It is unclear, and not explained in the specification, how one skilled in the art would use a gene construct or vector comprising the probe or primer. The probe or primer could be considered a molecule of, for example, part ii) of claim 80 or part (iv) of claim 86. However, sequences smaller than 23 nucleotides are known to be insufficient to down-regulate expression of a coding sequence. For example, Thomas et al. (Plant J., 2001, Vol. 25, pages 417-425) teaches that the lower size limit for silencing a GFP transgene is 23 nucleotides

(pages 418-419). The claimed gene construct and vectors comprising probes and primer sequences as small as 15 nucleotides could not be used to down regulate any endogenous starch synthase II genes. It is unclear how else one skilled in the art is to use the claimed gene constructs and vectors. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

9. Claims 71 and 73 are objected and claims 67-70, 72, 74, 75, 80, 82, 85-91 are rejected.

#### ***Contact Information***

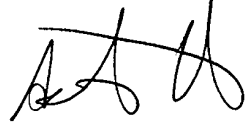
Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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January 26, 2005

A handwritten signature in black ink, appearing to read 'Ashwin D. Mehta'.

Ashwin D. Mehta, Ph.D.  
Primary Examiner  
Art Unit 1638